



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-P-2438]

#### **Determination That ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:** Donna Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993-0002, 301-796-3600, [Donna.Tran@fda.hhs.gov](mailto:Donna.Tran@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 mg, is the subject of NDA 021830, held by Allergan Pharmaceuticals International Ltd., and initially approved on May 29, 2008. ASACOL HD is indicated for the treatment of moderately active ulcerative colitis in adults.

In a letter dated May 13, 2022, Allergan Pharmaceuticals International Ltd. notified FDA that ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 mg, was being discontinued, and FDA moved the drug product to the “Discontinued Drug Product List” section of the Orange Book.

Aurobindo Pharma USA, Inc., submitted a citizen petition dated October 4, 2022 (Docket No. FDA-2022-P-2438), under 21 CFR 10.30, requesting that the Agency determine whether ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 mg, was not withdrawn for reasons of safety or

effectiveness. The petitioner has identified no data or other information suggesting that ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 mg, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 15, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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